

USSN 09/726470
Examiner: B. Dell Chism

20

Attorney Docket No.: CCI-014
Art Unit: 1635

REMARKS

Claims 1-62 are pending in this application. Claims 1-15 and 26-54 have been withdrawn as being directed to a non-elected invention. Claims 16, 20-22 and 25 have been amended. Claims 54-62 have been added. Accordingly, claims 16-25 and 54-62 are presently under consideration. Support for the amendments to the claims can be found throughout the specification and claims as originally filed.

Accordingly, no new matter has been added. The claim amendments requested herein should in no way be construed as acquiescence to any of the rejections and have been made solely to expedite prosecution of the application. Applicants reserve the right to pursue the claims as originally filed and/or prior to amendments made herein in this or a separate application(s).

Applicants gratefully thank the Examiner for the courtesy of the in-person interview held on June 25, 2003 with the undersigned, during which the outstanding rejections of record were discussed. In particular, as noted on the Interview Summary, draft claim amendments were discussed with respect to the rejections under 35 U.S.C. §112 for written description and enablement. Accordingly, a detailed description of the support for the claims as amended is included herein.

Claim Rejections Under 35 U.S.C. §112, second paragraph

Claims 16-21 and 25 have been rejected as being indefinite for the recitation of the term "any amino acid," on the ground that it is not clear whether this term can be natural or non-natural amino acids.

Applicants respectfully traverse this rejection. However, solely to expedite prosecution, the claims have now been amended to specify that "X₁, X₃, X₄ and X₅ are each a natural or unnatural amino acid." Accordingly, this rejection has been rendered moot.

USSN 09/726470
Examiner: B. Dell Chism

21

Attorney Docket No.: CCI-014
Art Unit: 1635

Claims 22-24 have been rejected as being indefinite for the recitation of the phrase "such as" on the ground that it is unclear whether the limitations following this phrase are part of the claimed invention.

These claims have been amended to remove the phrase "such as" thus rendering this rejection moot. In addition, new dependent claims 52-62 have been added to clarify that the embodiments set forth in claim 22 prior to the present amendment are indeed considered to be part of the claimed invention.

Claim Rejections Under 35 U.S.C §112, first paragraph

Claims 16-24 have been rejected as lacking sufficient written description on the ground that the claims encompass any peptide comprising the general formula II and variants thereof. Specifically, the Office Action states that "[o]ne of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises over 51 billion species." (Office Action at page 5)

Applicants respectfully traverse this rejection. It is the understanding of Applicants representative that this rejection is based, at least in part, on the Examiner's interpretation of the phrase "peptide of formula II" as encompassing all peptides comprising formula II. Accordingly, the claims have been amended to clarify that which Applicants view as their invention, *i.e.*, a "peptide consisting of the formula $X_1X_2X_3RX_4LX_5F$ (SEQ ID No. 2)." The amended claims further specify that certain amino acids can be substituted by natural or unnatural amino acids, examples of which are set forth in the specification, at least at, pages 24-25 and pages 47-50. Therefore, Applicants respectfully submit that, in view of the fact that more than 140 species (e.g., see pages 29-32, and Examples 13-21) of the claimed genus are disclosed in the instant specification, one of skill in the art would recognize that Applicants were in possession of the claimed invention as of the filing date of the present application. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 16-24 have also been rejected as lacking enablement. Specifically, the Office Action states that "[t]he breadth of the claims is inclusive to more than 51 billion

USSN 09/726470
Examiner: B. Dell Chism

22

Attorney Docket No.: CCI-014
Art Unit: 1635

possible compounds and/or structures, and other than the sequences disclosed on pages 29-33, the present application is not enabled for the multitude of other possible combinations of natural and/or unnatural amino acid substitutions, deletions and additions with or without chemical modifications." The Office Action further concludes that "the specification is without enablement insofar as [] it would require undue experimentation to confirm that 51 billion possible combinations and/or structures of general formula II maintain p21 activity."

Applicants respectfully traverse this rejection. As discussed above, the instant claims do not encompass a virtually infinite number of species, but are directed to a peptide consisting of $X_1X_2X_3RX_4LX_5F$ (SEQ ID No. 2), wherein certain amino acids may be deleted, substituted or modified. In support of the claimed invention, the specification describes, in detail, the three-dimensional interaction of the peptide HAKRRLLIF with cyclin A (see pages 37-42, Examples 4 and Example 27), and identifies the relative importance of each amino acid of the peptide involved in this interaction (see pages 38 and 94). Suitable software for generating three-dimensional models for any peptide is then provided in order to allow the skilled artisan to systematically examine peptides for the desired characteristics, and multiple methods of synthesizing peptides within the scope of the claimed invention are disclosed (e.g., see pages 50-51 and the Examples). Moreover, in Examples 13-23 variations of each amino acid, cyclic peptides and peptides with multiple substitutions are presented. In total, more than 140 species of the peptide having the claimed formula (SEQ ID No. 2) are disclosed (e.g., at pages 29-33 and 91-92). Accordingly, given the guidance of the present specification and the numerous examples provided, one of ordinary skill in the art would be able to synthesize and test any species within the scope of the claimed invention without undue experimentation.

For at least the foregoing reasons, Applicants respectfully submit that the presently claimed invention is fully enabled, and reconsideration and withdrawal of this rejection is respectfully requested.

USSN 09/726470
Examiner: B. Dell Chism

23

Attorney Docket No.: CCI-014
Art Unit: 1635

Claim Rejections under 35 U.S.C. §102(b)

Claims 16-25 have been rejected as being anticipated by Database PIR_73, AC S39358, 25 February 1994, and anticipated by Database Swill Prot_40, AC P38936, 15 December 1995.

Applicants respectfully traverse these rejections. The cited references disclose peptides of 47 and 181 amino acids in length, respectively. Thus, neither reference anticipates the claimed invention which is directed to a "peptide consisting of the formula $X_1X_2X_3RX_4LX_5F$ (SEQ ID No. 2). Accordingly, withdrawal of this rejection is respectfully requested.

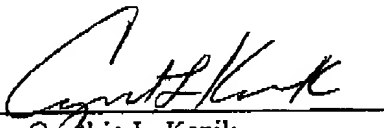
SUMMARY

In view of the remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' attorney would expedite the prosecution of the above-identified application, the examiner is urged to call Applicant's attorney at (617) 227-7400.

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